TITLE OF THE INVENTION

Inflatable Heat Transfer Apparatus

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of copending U. S. Application Ser. No. 09/414,184, for "Inflatable Cooling Apparatus for Selective Organ Hypothermia", filed 10/07/1999.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

Field of the Invention - The current invention relates to selective cooling, or hypothermia, of an organ, such as the brain, by cooling the blood flowing into the organ. This cooling can protect the tissue from injury caused by anoxia or trauma.

Background Information - Organs of the human body, such as the brain, kidney, and heart, are maintained at a constant temperature of approximately 37° C. Cooling of organs below 35° C is known to provide cellular protection from anoxic damage caused by a disruption of blood supply, or by trauma. Cooling can also reduce swelling associated with these injuries.

Hypothermia is currently utilized in medicine and is sometimes performed to protect the brain from injury. Cooling of the brain is generally accomplished through whole body cooling to create a condition of total body hypothermia in the range of 20° to 30° C. This cooling is accomplished by immersing the patient in ice, by using cooling blankets, or by cooling the blood flowing externally through a cardiopulmonary bypass machine.

Total body hypothermia to provide organ protection has a number of drawbacks. First, it creates cardiovascular problems, such as cardiac arrhythmias, reduced cardiac

output, and increased systemic vascular resistance. These side effects can result in organ damage. These side effects are believed to be caused reflexively in response to the reduction in core body temperature. Second, total body hypothermia is difficult to administer. Immersing a patient in ice water clearly has its associated problems. Placement on cardiopulmonary bypass requires surgical intervention and specialists to operate the machine, and it is associated with a number of complications including bleeding and volume overload. Third, the time required to reduce the body temperature and the organ temperature is prolonged. Minimizing the time between injury and the onset of cooling has been shown to produce better clinical outcomes.

Some physicians have immersed the patient's head in ice to provide brain cooling. There are also cooling helmets, or head gear, to perform the same. This approach suffers from the problems of slow cool down and poor temperature control due to the temperature gradient that must be established externally to internally. It has also been shown that complications associated with total body cooling, such as arrhythmia and decreased cardiac output, can also be caused by cooling of the face and head only.

Selective organ hypothermia has been studied by Schwartz, et. al. Utilizing baboons, blood was circulated and cooled externally from the body via the femoral artery and returned to the body through the carotid artery. This study showed that the brain could be selectively cooled to temperatures of 20° C without reducing the temperature of the entire body. Subsequently, cardiovascular complications associated with total body hypothermia did not occur. However, external circulation of the blood for cooling is not a practical approach for the treatment of humans. The risks of infection, bleeding, and fluid imbalance are great. Also, at least two arterial vessels must be punctured and cannulated. Further, percutaneous cannulation of the carotid artery is very difficult and potentially fatal, due to the associated arterial wall trauma. Also, this method could not be used to cool organs such as the kidneys, where the renal arteries cannot be directly cannulated percutaneously.

Selective organ hypothermia has also been attempted by perfusing the organ with a cold solution, such as saline or perflourocarbons. This is commonly done to protect the heart during heart surgery and is referred to as cardioplegia. This procedure has a number

of drawbacks, including limited time of administration due to excessive volume accumulation, cost and inconvenience of maintaining the perfusate, and lack of effectiveness due to temperature dilution from the blood. Temperature dilution by the blood is a particular problem in high blood flow organs such as the brain. For cardioplegia, the blood flow to the heart is minimized, and therefore this effect is minimized.

Intravascular, selective organ hypothermia, created by cooling the blood flowing into the organ, is the ideal method. First, because only the target organ is cooled, complications associated with total body hypothermia are avoided. Second, because the blood is cooled intravascularly, or in situ, problems associated with external circulation of blood are eliminated. Third, only a single puncture and arterial vessel cannulation is required, and it can be performed at an easily accessible artery such as the femoral, subclavian, or brachial. Fourth, cold perfusate solutions are not required, thus eliminating problems with excessive fluid accumulation. This also eliminates the time, cost, and handling issues associated with providing and maintaining cold perfusate solution. Fifth, rapid cooling can be achieved. Sixth, precise temperature control is possible.

The important factor related to catheter development for selective organ hypothermia is the small size of the typical feeding artery, and the need to prevent a significant reduction in blood flow when the catheter is placed in the artery. A significant reduction in blood flow would result in ischemic organ damage. While the diameter of the major vessels of the body, such as the vena cava and aorta, are as large as 15 to 20 mm., the diameter of the feeding artery of an organ is typically only 4.0 to 8.0 mm. Thus, a catheter residing in one of these arteries cannot be much larger than 2.0 to 3.0 mm. in outside diameter. The small size of the feeding artery also limits the size and type of heat transfer element that can safely be used.

A catheter based on the circulation of water or saline operates on the principle of transferring heat from the blood to raise the temperature of the water. Therefore, it is essential to use a heat transfer element that transfers heat from the blood to the cooling fluid as efficiently as possible, while restricting the flow of blood as little as possible. So, it would be beneficial to have a heat transfer apparatus that can be inserted

percutaneously into an artery of restricted size, that can efficiently transfer heat, and that will not significantly limit the flow rate of blood in the artery during application of cooling.

BRIEF SUMMARY OF THE INVENTION

The present invention is a cooling apparatus comprising a flexible catheter which can be inserted through the vascular system of a patient to a feeding artery, with an inflatable balloon heat exchanger near the distal end of the catheter. The present invention also encompasses a method for using such a device to perform selective organ cooling. After placement in the selected feeding artery, the heat exchanger balloon is inflated by pressurization with a saline solution, via a supply lumen in the catheter. The heat exchanger balloon has one or more blood passageways passing through it, from a proximal aspect of the balloon to a distal aspect of the balloon. When the heat exchanger balloon is inflated to contact the wall of the artery in which it is placed, each of the blood passageways comprises a tube having an inlet in one face of the heat exchanger balloon and an outlet in another face of the heat exchanger balloon, thereby allowing blood to continue flowing through the artery after inflation of the balloon. The blood passageway tubes can be constructed of a material having a relatively high thermal conductivity, such as a thin metallized polymer, such as a film with one or more metallized surfaces. Alternatively, the blood passageway tubes can be constructed of a metal-loaded polymer film. Further, the entire heat exchanger balloon can be constructed of such a material, in order to maximize the cooling capacity of the heat exchanger.

After inflation of the heat exchanger balloon, the saline solution, which is chilled by an external chiller, continues circulating through the interior of the heat exchanger balloon, around the blood passageway tubes, and back out of the balloon through a return lumen in the catheter. This cools the blood passageway tubes, which in turn cool the blood flowing through them. This cooled blood then flows through the selected organ and cools the organ.

The device can also incorporate a lumen for a guidewire, facilitating the navigation of the catheter through the vascular system of the patient.

The novel features of this invention, as well as the invention itself, will be best understood from the attached drawings, taken along with the following description, in which similar reference characters refer to similar parts, and in which:

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Figure 1 is a perspective view of the device of the present invention in place in a common carotid artery of a patient;

Figure 2 is a perspective view of the device shown in Figure 1, with additional details of construction;

Figure 3 is a transverse section view of the device shown in Figure 2, along the section line 3-3; and

Figure 4 is a partial longitudinal section view of the device shown in Figure 2, showing the flow path of the cooling fluid.

DETAILED DESCRIPTION OF THE INVENTION

As shown in Figure 1, the cooling apparatus 10 of the present invention includes a flexible multilumen catheter 12, an inflatable balloon 14, and a plurality of blood flow passageways 16 through the balloon 14. The balloon 14 is shown in an inflated state, in a selected position in a common carotid artery CC.

The balloon 14 is attached near a distal end of the flexible catheter 12. The catheter 12 can have at least a cooling fluid supply lumen 18 and a cooling fluid return lumen 20, with the cooling fluid supply lumen 18 preferably being located substantially within the cooling fluid return lumen 20. The catheter 12 can also have a guidewire lumen 22, for the passage of a guidewire 24, as is known in the art.

The balloon 14 can be formed from a flexible material, such as a polymer. The balloon 14 can be constructed to assume a substantially cylindrical shape when inflated, with a proximal aspect 15 and a distal aspect 17. The balloon 14 can have a plurality of tubular shaped blood flow passageways 16 formed therethrough, from the proximal aspect 15 to the distal aspect 17. The tubular walls of the passageways 16 constitute a

heat transfer surface, for transferring heat from the blood to the cooling fluid. The flexible material of the tubular passageways 16 can be, at least in part, a metallized material, such as a film coated with a thin metal layer, either internally, externally, or both, to aid in heat transfer through the passageway walls. Alternatively, the tubular passageways 16 can be constructed of a metal-loaded polymer film. Further, the remainder of the balloon 14 can be coated with a thin metallized layer, either internally, externally, or both, or a metal-loaded polymer film. The proximal aspect 15 and the distal aspect 17 of the balloon can also constitute a heat transfer surface, for transferring heat from the blood to the cooling fluid. The guidewire lumen 22 of the catheter 12 can also pass through the balloon 14, from the proximal aspect 15 to the distal aspect 17.

As shown in Figure 2, each tubular passageway 16 has a proximal port 26 in a proximal face 28 on the proximal aspect 15 of the balloon 14, and a distal port 30 in a distal face 32 on the distal aspect 17 of the balloon 14. A cooling fluid supply port 34 near the distal end of the cooling fluid supply lumen 18 supplies chilled saline solution from a chiller (not shown) to the interior of the balloon 14, surrounding the blood flow passageways 16. A cooling fluid return port 36 in the cooling fluid return lumen 20 returns the saline solution from the interior of the balloon 14 to the chiller. Relative placement of the cooling fluid ports 34, 36 can be chosen to establish flow counter to the direction of blood flow, if desired.

Figure 3 shows the proximal aspect 15 of the balloon 14 and gives a view through the blood flow passageways 16, illustrating the general arrangement of the blood flow passageways 16, cooling fluid supply lumen 18, cooling fluid return lumen 20, and guidewire lumen 22, within the outer wall 38 of the balloon 14. Figure 4 is a side elevation view of the apparatus 10, with a partial longitudinal section through the balloon wall 38, showing one possible arrangement of the cooling fluid supply port 34 and the cooling fluid return port 36 within the balloon 14.

In practice, the balloon 14, in a deflated state, is passed through the vascular system of a patient on the distal end of the catheter 12, over the guidewire 24. Placement of the guidewire 24 and the balloon 14 can be monitored fluoroscopically, as is known in the art, by use of radiopaque markers (not shown) on the guidewire 24 and the balloon 14.

When the balloon 14 has been positioned at a desired location in the feeding artery of a selected organ, such as in the common carotid artery feeding the brain, fluid such as saline solution is supplied through the cooling fluid supply lumen 18. This fluid passes through the cooling fluid supply port 34 into the interior of the balloon 14, surrounding the tubular passageways 16, to inflate the balloon 14. Although the balloon 14 can be formed to assume a substantially cylindrical shape upon unconstrained inflation, the balloon 14 will essentially conform to the shape of the artery within which it is inflated. As the balloon 14 inflates, the blood flow passageways 16 open, substantially assuming the tubular shape shown.

When the balloon 14 has been properly inflated, blood continues to flow through the feeding artery CC by flowing through the blood flow passageways 16, as indicated, for example, by the arrows in Figure 1. The size and number of the blood flow passageways 16 are designed to provide a desired amount of heat transfer surface, while maintaining a suitable amount of blood flow through the feeding artery CC. Return flow to the chiller can be established, to allow flow of cooling fluid through the cooling fluid return port 36 and the cooling fluid return lumen 20 to the chiller. This establishes a continuous flow of cooling fluid through the interior of the balloon 14, around the blood flow passageways 16. The return flow is regulated to maintain the balloon 14 in its inflated state, while circulation of cooling fluid takes place. The saline solution is cooled in the chiller to maintain a desired cooling fluid temperature in the interior of the balloon 14, to impart a desired temperature drop to the blood flowing through the tubular passageways 16. This cooled blood flows through the feeding artery to impart the desired amount of cooling to the selected organ. Then, cooling fluid can be evacuated or released from the balloon 14, through the catheter 12, to deflate the balloon 14, and the apparatus 10 can be withdrawn from the vascular system of the patient.

While the particular invention as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages hereinbefore stated, it is to be understood that this disclosure is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended other than as described in the appended claims.